REMARKS

Claims 1 to 40 and 42 to 53, as amended, appear in this application for the Examiner's review and consideration. Claims 1 to 32, 39, 40, and 46 to 53 have been withdrawn from consideration, as being drawn to non-elected subject matter. Claims 33-38 and 42-45 are currently rejected. Claims 42 and 43 have been amended, support for the amendment can be found in the specification on page 7, first paragraph, and on page 13, table 1.

1. Claims 33-38 and 42-45 are rejected under 35 U.S.C. 102(a), (b) and/or (e) as being anticipated.

The Examiner has rejected claims 33-38 and 42-45 as being anticipated by Vercer et al., Kotar et al., Choi et al., Nohara et al., Kato et al., and Avrutov et al. I, and II. According to the Examiner the cited references specifically disclose the claimed compound and compositions. Further, the Examiner asserts that a novel chemical product is identified first by its "chemical nature", i.e. elemental and atom content, and that it is a well known fact that many pharmaceutical solids exhibit polymorphism. According to the Examiner polymorphs are different arrangements and/or different conformations of the **same pure substance**. The Examiner alleges that applicant's arguments do not take place of objective evidence showing the alleged "stable" compound is any different from the prior art.

In response, Applicants submit that, as recited in claims 33 to 38, the presently claimed invention is directed to a chemically stable lansoprazole, prepared by the process of the invention. As recited in claims 42 and 43, the presently claimed invention is directed to a chemically stable lansoprazole, comprising less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative, upon exposure to a relative humidity of 75% at 40°C for a period of at least about three months and for a period of at least about six months, respectively. As recited in claims 44 and 45, the presently claimed invention is directed to a chemically stable lansoprazole that does not change color upon exposure to a relative humidity of 75% at 40°C for a period of at least about three months.

In contrast to the Examiner's assertions the claimed invention is not to a chemically pure substance or a particular crystalline polymorph thereof but to a stable lansoprazole which contains impurities as described in the specification. The present claims and the specification and claims, as originally filed, are clearly not directed to only chemically pure substances. Instead, as originally filed, claims 33 to 35 and 41 were all directed to a stable

lansoprazole, claims 36 to 38 were all directed to a pharmaceutical composition, comprising a stable lansoprazole, and claims 42 and 43 were directed to a lansoprazole. As discussed below, one of ordinary skill in the art would understand that a lansoprazole, as with any material, will almost invariably contain impurities, and, thus, will not be a chemically pure compound, even at an extremely high purity. In addition, claims 42 and 43, as originally filed, were clearly directed to a lansoprazole that can comprise additional elements. In particular, claims 42 and 43, as originally filed, recite:

> 42. A lansoprazole containing less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative, upon exposure to a relative humidity of 75% at 40°C for a period of at least about three months.
> 43. A lansoprazole, containing less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative, upon exposure to a relative humidity of 75% at 40°C for a period of at least about six months.

Therefore, the original claims were not drawn to the chemical compounds only. That is the originally filed claims were not directed to a chemically pure lansoprazole compound. Instead, the originally filed claims were drawn to a stable lansoprazole and to pharmaceutical compositions, comprising the stable lansoprazole. As will be understood by one of ordinary skill in the art, a lansoprazole, as recited in originally filed claims 42 and 43, will likely contain at least one impurity.

Moreover, one of ordinary skill in the art, in light of the present specification, would clearly understand that the present invention is directed to a stable lansoprazole that may contain impurities. At various places in the specification, the presence of impurities in lansoprazole is disclosed. For example, at page 2, first paragraph, the present specification teaches

> The preparation of lansoprazole by conventional methods is generally accompanied by the formation of small quantities of the corresponding sulfone derivative as an impurity.

At page 7, first paragraph, the present specification teaches that

> "LNPS" refers to the sulfide-containing starting compound for lansoprazole preparation. The chemical name for LNPS is 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinil]thio]-lH benzimidazole. "LNP" refers to lansoprazole which has the chemical name of 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl]sulfinyl-1 H benzimidazole. The present invention provides a lansoprazole that contains less than about 0.1% (Mwt) sulfone derivative and less than about 0.1% sulfide derivative (i.e., substantially free of sulfone and sulfide).

At page 8, sixth paragraph, the present specification teaches:

> Although the lansoprazole obtained by the above-mentioned crystallization process can be advantageous, it cannot be dried to <0.1% water as required by the USP forum.

Further disclosures of impurities in lansoprazole can be found in the Examples on pages 12 to 14. Therefore, the specification and the claims, as originally filed, clearly teach that the chemically stable lansoprazole of the presently claimed invention can also comprise impurities.

Further, as demonstrated by objective evidence in Examples 2 and 3 of the present specification, the presently claimed stable lansoprazole is substantially more chemically stable than prior art lansoprazole. After one month at a temperature of 40°C and a relative humidity of 75 percent, none of the sulfone compound can be detected in the chemically stable lansoprazole of the invention, which remains white. In contrast, after one month under the same conditions, the non-stabilized, prior art lansoprazole contains 0.03 percent of the sulfone compound, and has changed color. Present specification, Example 2, pages 12 and 13. Similarly, after three months at 40°C and a relative humidity of 75 percent, the chemically stable lansoprazole composition of the invention contains only 0.03 percent of the sulfone compound, and remains white. In contrast, under the same conditions, the non-stabilized, prior art lansoprazole contains 0.06 percent of the sulfone compound, and has changed color. Present specification, Example 3, pages 13 and 14.

Although the cited prior art references may disclose lansoprazole and polymorphs of lansoprazole, the references disclose non-stable, prior art lansoprazole, not the presently claimed chemically stable lansoprazole composition.

In contrast to the presently claimed invention, Vrečer discloses the relative physical stability of polymorphic forms A and B of prior art lansoprazole. In particular, Vrečer discloses that lansoprazole polymorphic form B is not physically stable, and transforms to polymorphic form A on heating. Vrečer discloses only non-stable, prior art lansoprazole, and, thus, Vrečer does not disclose a chemically stable lansoprazole composition, as presently claimed as Vrečer does not stabilize its crystalline lansoprazole to provide chemically stability. Therefore, Vrečer does not anticipate the present claims.

Similarly, Kotar discloses the analysis of polymorphs of prior art lansoprazole, and that lansoprazole form B is not stable, undergoing a solid-solid transition to form A. For the same reasons with respect to Vrečer, Kotar discloses only non-stable, prior art lansoprazole,

and, thus, Kotar does not disclose the presently claimed chemically stable lansoprazole composition, and, thus, does not anticipate the present claims.

Choi discloses a process for preparing conventional prior art sulfoxide compounds, such as lansoprazole, comprising oxidizing a sulfide compound with hydrogen peroxide in the presence of a rhenium catalyst. The disclosed process reportedly minimizes the production of N-oxide and sulfone byproducts. Page 1, lines 4 to 17. The m-chloroperbenzoic acid, used in the prior art as the oxidizing agent, reportedly results in the formation of the N-oxide and sulfone byproducts, resulting in a low yield in the preparation. Page 3, lines 9 to 22. Other prior art processes, such as the oxidation of the sulfide compound with hydrogen peroxide in the presence of a vanadium catalyst, reportedly result in the production of more than 1 HPLC area percent of the sulfide compound and a product containing 0.4% after purification. Page 6, lines 2 to 9, and page 7, lines 1 to 11. The disclosed process reportedly minimizes the production of the N-oxide and sulfone by products, and removes the by products by filtration.

Choi discloses a non-stable, prior art lansoprazole, and, thus, does not disclose the chemically stable lansoprazole composition of the presently claimed invention. Therefore, as Choi discloses a conventional lansoprazole, not the chemically stable lansoprazole composition of the present invention, the present claims are not anticipated by Choi.

Nohara discloses 2-[2 pyridylmethylthio-(sulfinyl)-] benzimidazoles and processes for preparing such compounds. A sulfide derivative, prepared with the disclosed process, can be oxidized to prepare a sulfinyl derivative. Column 2, lines 21 to 48. Compounds produced with the disclosed process "can be isolated and purified by conventional means, e.g., crystallization and chromatography." Column 2, lines 66 to 68.

Nohara discloses only non-stable, prior art lansoprazole, and, thus, does not disclose the presently claimed chemically stable lansoprazole composition. Therefore, the present claims are not anticipated by Nohara.

Kato discloses a prior art, substantially solvent-free lansoprazole that is free of decomposition in the course of vacuum drying. Column 2, lines 22 to 26. Kato further discloses that, unless the lansoprazole is desolvated in accordance with the disclosed process, attempting to desolvate the compound by vacuum drying negatively affects the stability of the product. Column 1, lines 48 to 57, and column 2, lines 21 to 26.

Kato does not disclose a lansoprazole composition, having long term chemical stability, i.e., for over three to six months, as does the presently claimed chemically stable

lansoprazole composition, which is stabilized by isolating and/or drying the lansoprazole composition in the presence of a relatively large amount of a weak base, such as ammonia. In Example 1, Kato discloses a process for the production of such a solvent-free lansoprazole in which 13 g of lansoprazole was crystallized from a solution comprising 75 ml of a 9:1 ethanol-water mixture and 70 μl of a 25 percent aqueous ammonia solution. As the molecular weight of lansoprazole is 363.97, 13g of that compound corresponds to 0.035 moles or 35 mmol. Assuming a density of from about 0.9 to 1 for a 25 percent ammonia solution, as the molecular weight of ammonia is 17.03, 70 μl of such a solution contains about 0.9 to about 1 mmol of ammonia. Therefore the amount of ammonia present in the solution of Example 1 is only about 2.6 to 2.9 mole percent of the amount of lansoprazole, i.e., a mole ratio of about 0.03:1. That amount is significantly less than the equimolar amount presently claimed, and is not sufficient to provide the chemical stability of the presently claimed lansoprazole.

Similarly, in Comparative Example 1, Kato discloses crystallizing 10 g of lansoprazole from a solution comprising 58 ml of a 9:1 ethanol-water mixture and 54 μl of a 25 percent aqueous ammonia solution. Therefore, the amount of ammonia present is from about 0.71 to about 0.79 mmol, and the amount of lansoprazole is about 27 mmol, and, thus, the amount of ammonia is only about 2.6 to about 2.9 percent of the amount of lansoprazole, again, a mole ratio of about 0.03:1. Such a small amount of ammonia is not sufficient to provide the chemical stability of the presently claimed lansoprazole.

As discussed at page 2 of the present specification, the 0.03 moles of ammonia per mole of lansoprazole used in the Kato examples is only a trace amount, and is not sufficient to provide a chemically stable lansoprazole composition. As a result, the lansoprazole prepared by the processes disclosed by Kato will be chemically unstable during storage. Therefore, Kato does not disclose the presently claimed chemically stable lansoprazole composition, and, thus, Kato does not anticipate the present claims.

Avrutov discloses processes for preparing substituted 2-(2-pyridylmethyl)sulfinyl-1-H-benzimidizoles. Avrutov I and II, page 1, paragraph [0002]. In particular, Avrutov discloses a selective oxidation process for preparing lansoprazole. Avrutov I, page 2, paragraph [0016]; Avrutov II, page 2, paragraph [0025].

Avrutov discloses only non-stable, prior art lansoprazole. Therefore, Avrutov does not disclose the presently claimed invention, and the present claims are not anticipated by Avrutov.

Therefore, as none of Vrečer, Kotar, Choi, Nohara, Singer, Kato, and Avrutov disclose the presently claimed invention, the present claims are not anticipated by those references. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 33 to 38 and 41 to 45 under 35 U.S.C. §102(a), (b), and/or (e).

2. Claims 33-38 and 42-45 were rejected under 35 U.S.C. 103(a) as being obvious.

The Examiner has rejected claims 33-38 and 42-45 as being obvious over the combined teachings of Vercer et al., Kotar et al., Choi et al., Nohara et al., Kato et al., and Avrutov et al. I, and II in view of Hableblian et al., Chemical & Engineering News, US Pharmacopeia, Muzaffar et al, Jain et al, Taday et al, Concise Encyclopedia Chemistry and Brittain et al. (Polymorphism in Pharmaceutical Solids, pages 1-2, 185). Again, according to the Examiner the cited primary references teach the stable crystal forms of the instant known compound and as well as the pharmaceutical compositions. In addition, the Examiner asserts that the remaining references teach that compounds exist in different crystalline forms and that at any particular temperature and pressure only one crystalline form is thermodynamically stable. The Examiner alleges that hence the claimed crystalline form as well as its relative selectivity of properties vis-à-vis the known compound are suggested by the references. According to the Examiner it is obvious in view of the references that the compound would exist in different stable crystalline forms. Moreover, the Examiner asserts that the claimed subject matter differ from the known product merely by forms and the physical properties innate to the forms stating that the claims are drawn to the same pure substance as the prior art that only have different arrangements and/or different conformations of the molecule.

In response, Applicants submit that the claimed invention is directed to a chemically stable lansoprazole whether crystalline or not. The method of preparing the chemically stable lansoprazole, presently claimed contains a crystallization step. However, the claimed invention is not a crystalline form of lansoprazole but a chemically stable lansoprazole. Lansoprazole is chemically instable because of its inclusion of solvent (such as water) when crystallized. The chemically instability of solvated lansoprazole is attributed to proton attack of lansoprazole at the sulfur atom resulting in the appearance of its derivatives, the sulfide derivative 2-[[3-methyl-4-(2,2,2-trifluorethoxy)-2-pyridinil]thio]-1H benzimidazole and the sulfone derivative 2-[[3-methyl-4-(2,2,2-trifluorethoxy)-2-pyridinil]sulfonyl]-1H benzimidazole, which are considered impurities. The presently claimed invention is directed

to lansoprazole which is stable, i.e. is less prone to chemically instability, and the specification specifically discloses the claimed compound and compositions. None of the cited references disclose or suggest the chemically stable lansoprazole composition of the presently claimed invention.

As discussed above, Vrečer discloses the relative physical stability of polymorphic forms A and B of lansoprazole. In particular, Vrečer discloses that lansoprazole polymorphic form B is not physically stable, and transforms to polymorphic form A on heating. However, Vrečer does not disclose or suggest a chemically stable lansoprazole composition, as presently claimed.

Kotar discloses the analysis of the lansoprazole polymorphs, and that lansoprazole form B is not stable, undergoing a solid-solid transition to form A. Kotar does not disclose or suggest the presently claimed chemically stable lansoprazole composition.

Choi discloses a process for preparing conventional prior art sulfoxide compounds, such as lansoprazole, comprising oxidizing a sulfide compound with hydrogen peroxide in the presence of a rhenium catalyst. Choi discloses only non-stable, prior art lansoprazole, produced with the disclosed process, and, thus, does not disclose or suggest the presently claimed chemically stable lansoprazole composition.

Nohara discloses benzinidazoles and processes for preparing such compounds. The disclosed compounds are not the chemically stable lansoprazole composition of the presently claimed invention. Instead, Nohara discloses only non-stable, prior art, lansoprazole. Therefore, Nohara does not disclose or suggest the presently claimed chemically stable lansoprazole composition.

Kato discloses a substantially solvent-free lansoprazole that is free of decomposition in the course of vacuum drying. Kato does not disclose or suggest a lansoprazole, having chemical stability over three to six months, as does the presently claimed chemically stable lansoprazole composition. The 0.03 moles of ammonia per mole of lansoprazole used in the Kato examples is only a trace amount, and is not sufficient to provide a chemically stable lansoprazole. As discussed above and at page 2 of the present specification, the lansoprazole prepared by the processes disclosed by Kato will be chemically unstable. Therefore, Kato does not disclose or suggest the presently claimed chemically stable lansoprazole composition.

Avrutov discloses processes for preparing substituted 2-(2-pyridylmethyl)sulfinyl-1-H-benzimidizoles. Avrutov discloses only non-stable, prior art lansoprazole, and does not disclose or suggest the chemically stable lansoprazole composition of the presently claimed invention.

As stated in the Office Action at page 4, Hableblian, Muzaffar, Jain, and Taday each teach that some crystalline compounds can exist in different crystalline forms. The Office Action also states, at page 4, that C & E News, Muzaffar, U.S. Pharmacopia, and Concise Encyclopedia of Chemistry all teach that, at any particular temperature and pressure, only one crystalline form is thermodynamically stable.

However, as discussed above, the presently claimed invention is directed to a chemically stable lansoprazole composition, not a thermodynamically stable polymorphic form. None of the cited references whether taken alone or in combination, disclose or suggest the presently claimed chemically stable lansoprazole composition. Instead, the cited prior art references discloses only non-stable, prior art lansoprazole.

Therefore, as the cited references, whether taken alone or in combination do not disclose or suggest the presently claimed invention, the claims are not obvious over these references. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 33 to 38 and 41 to 45 under 35 U.S.C. §103(a).

3. Claims 33-38 and 42-45 were rejected under 35 U.S.C. 112, first paragraph.

Claims 33 to 38 and 42 to 45 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, for the reasons set forth on pages 5 to 10 of the Office Action.

In particular, the rejection is based on the possibility of a change in polymorphic state of a crystalline form of a compound during storage or tablet preparation. The Office Action, at page 7, states

> The specification lacks description of how the pharmaceutical composition can be prepared in order to maintain the particular compound of a particular form with the particular infrared and x-ray diffraction being claimed .... Disclosure of x-ray diffraction patterns for the compounds and pharmaceutical compositions comprising the polymorphic forms are lacking in the specification. The specification has also not described how the stable form and composition's being claimed will be maintained and prevented from converting to other forms .....

Further, according to the Examiner, "Applicants have provided no objective evidence that the instant stable form will not be identical to the prior art compound because when a crystalline solid is dissolved in solvent, the crystalline structure is lost so that different polymorphs of the same substance will show the same absorption spectra as solution." Moreover, the Examiner asserts that there is no description or enabling support that the instant polymorph will be in its physical form and biological activity results from the particular form instead of the solution stat of the compound.

In response, Applicants respectfully submit that XRD and IR spectra are not provided, and there is no teaching in the specification on how to maintain a particular polymorphic form because a new polymorphic crystalline form of lansoprazole is not disclosed or claimed in the present application. The presently claimed invention is directed to a chemically stable lansoprazole. That is, the presently claimed invention is a lansoprazole, produced in a known process, that is then stabilized with the method of the invention, providing the chemically stable lansoprazole of the invention. As the present claims are not directed to a new polymorphic crystalline form, no XRD or IR spectral data are required. No disclosure of how to prevent the lansoprazole of the invention from converting to a different polymorphic form is provided, because the invention is not directed to a polymorphic form.

At pages 1 to 3, the present specification discusses the instability of prior art lansoprazole. As will be understood by one of ordinary skill in the art, the instability of lansoprazole discussed in the specification is not a polymorphic instability. Instead, the instability discussed in the specification is a chemical instability, the conversion of the lansoprazole compound to other chemical compounds such as its sulfide or sulfone derivative. When prior art lansoprazole is stored or exposed to heat and humidity, a chemical change occurs, producing impurities in the form of different chemical compounds, not different polymorphic forms. At page 3, lines 1 to 11, the present specification states that during storage, prior art lansoprazole degrades, such that the concentration of lansoprazole decreases, resulting in discoloration. Degradation of a compound results from a chemical change, not a change in polymorphic form, as alleged in the Office Action.

Moreover, the present specification clearly teaches one of ordinary skill in the art how to make and use the invention, and the specification describes the claimed subject matter in such a way as to reasonably covey to one skilled in the relevant art that the Applicants had possession of the claimed invention at the time the application was filed.

In the first paragraph of each of pages 2 and 7, the specification discloses the impurities that are formed in lansoprazole during synthesis and storage. The impurities are further disclosed in Tables 1 and 2 on pages 13 and 14, respectively. Processes for preparing the presently claimed chemically stable lansoprazole are set forth in both the Summary and Detailed Description sections of the specification, and are particularly exemplified in Examples 2 and 3 on pages 12 to 14 of the specification. The superior chemical stability of the presently claimed chemically stable lansoprazole, compared to the prior art lansoprazole, is set forth in the aforementioned Tables 1 and 2.

Clearly, one of ordinary skill in the art would understand how to make and use the presently claimed invention from the present specification.

With respect to an alleged lack of description as to whether the pharmaceutical carriers are able to maintain the compound in the stable form claimed, one of ordinary skill in the art, in light of the specification, would understand how to make and use the presently claimed pharmaceutical compositions. Pharmaceutical carriers, diluents, disintegrates, binders, giants, dyes, colorants, lubricants, excipients, and the like, useful in the invention, are set forth on pages 9 to 12.

Therefore, as the presently claimed invention is not directed to stable polymorphs, but, instead, is directed to a chemically stable lansoprazole, the present specification clearly teaches one of ordinary skill in the art how to make and use the claimed invention, and, thus, the claims meet the requirements of 35 U.S.C. §112, first paragraph. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 33 to 38 and 42 to 45 under 35 U.S.C. § 112, first paragraph.

4. Claims 33-38 and 42-45 were rejected under 35 U.S.C. 112, second paragraph for being indefinite.

Claims 33 to 38 and 42 to 45 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for the reasons set forth on pages 10-12 of the Office Action.

According to the Examiner, claims 33-35 are improper product-by-process claims, as such claims are improper in the same application where it has been demonstrated that the compound in question may be described by means of a chemical structure.

In response Applicants submit that claims 33-35 are directed to a stable lansoprazole. Lansoprazole, is an active pharmaceutical ingredient which may include some amount of other chemical compounds, other than the pure chemical compound lansoprazole, such as the

previously described impurities. Although the chemical compound 2-[[[3-methyl-4-(2,2,2-trifluorethoxy)-2-pyridinyl]methyl]sulfinyl]-1H benzimidazole (lansoprazole) can be described by its chemical structure the presently claimed stable lansoprazole, which comprises the chemical compound lansoprazole and small amounts of impurities, may not be readily described by the chemical structure of the compound. Further, the level of impurities and the chemical stability of the claimed lansoprazole is a result of the claimed process. For these reasons, Applicants submit that product-by-process claims 33-35 are proper.

With regard to the recitation of "containing" in claims 42 and 43, during the August 17, 2005, telephone conference, the Examiner stated that the present claims were directed to a compound, and, thus, could not be open ended. Applicants understand this to mean that a compound has a specific structure that cannot be modified without changing the compound to a different compound. Moreover, as discussed above, in the April 3, 2006, interview, the Examiner stated that the election was to the compound lansoprazole only, and, as a result, it is Applicants understanding that the Examiner has apparently defined the claimed stable lansoprazole as chemically pure lansoprazole.

In response, as discussed above, Applicants submit that one of ordinary skill in the art would understand that any given sample of the active pharmaceutical ingredient lansoprazole contains lansoprazole and some amount of impurities. Even with the presently claimed chemically stable lansoprazole, it is practically impossible to remove all impurities, although the amount of any impurities in the presently claimed chemically stable lansoprazole increases significantly more slowly during storage than does the amount in prior art lansoprazole. Thus, one of ordinary skill in the art would understand that the "stable lansoprazole" of the present invention is actually a lansoprazole composition that may contain various impurities, including the sulfone and sulfide derivatives recited in claims 42 and 43. Accordingly, Applicants did contemplate the inclusion of other parameters not recited in the claims, and, thus, the present claims may be open ended, and meet the requirements of 35 U.S.C. § 112.

With regard to the recitation of sulfone derivative and sulfide derivative in claims 42 and 43, the Examiner asserts these terms are indefinite to their meaning. Although Applicants believe that those terms are clearly defined at the first paragraph of each of pages 2 and 7 and in Tables 1 and 2 on pages 13 and 14 of the specification, respectively, and, thus, would be understood by one of ordinary skill in the art, Applicants have amended claims 42

and 43 reciting the sulfone and sulfide derivative to more clearly define the claimed subject matter.

With regard to the recitation of the term "lansoprazole" in claims 33-38 and 42-45, the Examiner asserts that where the generic name lansoprazole is used in a claim as a limitation to identify or describe a particular material or product, the claim doe not comply with 35 U.S.C. § 112, second paragraph. The Examiner cites *Ex Parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). According to the Examiner the claim scope is uncertain since the generic name cannot be used to properly identify any particular material or product. The Examiner asserts that a generic name is used to identify a source of goods, and not the goods themselves.

In response, Applicants submit that contrary to the Examiner's assertions a generic name does not identify a source of goods, but identifies the goods themselves. The Examiner has confused the terms "generic name" and "trade name." A "trade name" identifies a source of goods. The term "lansoprazole" is not a trade name but a generic name for the chemical entity. Lansoprazole is an active pharmaceutical ingredient marketed under the trade name PREVACID in the United States. For this reason, Ex Parte Simpson, cited by the Examiner, does not apply as it relates to the use of trade names. Applicants submit that the term lansoprazole identifies an active pharmaceutical ingredient regardless of its source and therefore clearly identifies and describes the claimed subject matter in claims 33-38 and 42-45.

With respect to the alleged lack of antecedent basis for the recited limitations in claim 45, the Examiner asserts that there is no basis for the term "six months" in claim 45. In response, Applicants submit that claim 44 from which claim 45 depends recites "for at least about three months," which includes the limitation of "at least about six months." Therefore, the above identified recitation in claim 44 provides the necessary antecedent basis for the term "at least about six months." A term also found in claim 45 as originally filed.

Therefore, the claims particularly point out and distinctly claim the subject matter Applicants regard as the invention. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of claims 33 to 38 and 42 to 45 under 35 U.S.C. §112, second paragraph.

5. Claims 33-38 and 42-45 were provisionally rejected under the judicially created doctrine of obviousness type double patenting.

Claims 33-38, and 42-45 are provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-7 and 29-38 of copending U.S. Application Ser No. 10/717,325 in view of Haleblian et al., Chemical & Engineering News, US Pharmacopeia, Muzaffar et al, Jain et al, Taday et al, Concise Encyclopedia Chemistry and Brittain et al. (Polymorphism in Pharmaceutical Solids, pages 1-2, 185). According to the Examiner the stable compound and compositions are disclosed in this copending application. In response, Applicants wish to defer filing a terminal disclaimer until the currently pending claims are deemed allowable, at which time, Applicants intend to file a terminal disclaimer.

Applicants thus submit that the entire application is now in condition for allowance, an early notice of which would be appreciated. Should the Examiner not agree with Applicants' position, a personal or telephonic interview is respectfully requested to discuss any remaining issues prior to the issuance of a further Office Action, and to expedite the allowance of the application.

A separate Petition for Extension of Time is submitted herewith. Should any additional fees be due, however, please charge such fees to Deposit Account No. **11-0600**.

Respectfully submitted,

KENYON & KENYON LLP

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By: _____
Willem F.C. de Weerd
Reg. No. 51,613
One Broadway
New York, NY 10004
(212) 425-7200